STATE MEDICAID DUR BOARD MEETING

THURSDAY, March 9, 2006
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:

Derek G. Christensen, R.Ph.
Dominic DeRose, R.Ph.
Bradford D. Hare, M.D.
Jeff Jones, R.Ph.
Wilhlem T. Lehmann, M.D.
Bradley Pace, PA-C
Colin B. VanOrman, M.D.
Don Hawley, D.D.S.

Board Members Excused:

Lowry Bushnell, M.D.
Karen Gunning, Pharm D.
Charles M. Arena, M.D.
Joseph K. Miner, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Rae Dell Ashley, R.Ph.
Tim Morley, R.Ph.
Richard Sorenson, R.N.
Suzanne Allgaier, R.N.
Merelynn Berrett, R.N.
Brenda Strain

Other Individuals Present:

Capp Ferry, LEC
Lindsay Kerr, MD
Alan Sloan, Purdue
Alan Bailey, Pfizer
Richard Shanteau, Wasatch MH
Craig Boody, Lilly
Pamela Call-?
Kevin Stigge, MD
Owen Boyer, Pfizer
Mary Haupt, Pfizer
Matt Johnson, Takeda
Rich Heddens, Medimmune
Tim Smith Pfizer
Stuart Landau, MD
Todd Jankowski, BMS
Lonnie L., Pfizer
Joseph Yau, VMH
Georgette Dzwilewski, RB
JJ Roth, Pfizer

Meeting conducted by: Tim Morley

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1. Minutes for January 12, 2006 were reviewed, corrected and approved.

2. Housekeeping: a. Don Hawley, DDS introduced as interim Dentist on the Board
   b. Appointment dates and e-mails requested of board memebers
3. Business Carried Forward: none

4. Botox- Tim outlined the issue surrounding Botox. It is an injectable medication available through the physicians office via J-code billing. This medication has more off-labeled uses than approved uses. There is a need to control usage outside the physicians office setting when obtained through point-of-sale (POS) at the pharmacy. Botulinium comes in two types: Type A and Type B. Type A has four indications: Cervical Dystonia, Axillary

hyperhidrosis, blepharospam and strabismus associated with dystonia, and glabellar lines. The department proposes coverage for cervical dystonia, blepharospasm and strabismus. Type B has a single indication of cervical dystonia. Neither is approved for individuals under 12 years of age. The department proposes a prior authorization for provision through the pharmacy. Brad Hare noted that these drugs need very special application when being administered and should be done under the direct supervision of a physician. For this reason it is recommended to be used in the physicians office. RaeDell mentioned that many offices want to give it off-label and that needs to be considered client by client. Brad noted that when using for muscle pain in general the outcomes have not been good, meaning that there are some uses that are not appropriate. Tim pointed out the cost and dosage requirements, and outlined the proposed criteria for coverage through the POS for two indications: Cervical dystonia, blepharospasm and strabismus (which are considered one indication) for Type A (Botox) and one indication, cervical dystonia for Type B (Myobloc). All other requested uses will necessitate a petition to the DUR Board. The criteria are :

1) Written prior obtained by the physician
2) Documentation of the diagnosis
3) Documentation and history of other treatments
4) Letter of Medical Necessity
5) Patients aged 12 and older
6) Treatments every 3 months
7) Cumulative dose not to exceed 300 units (type A) or 10,000 units (type B) every 90 days

A point of clarification was requested by a public member, i.e. what is the avenue for a PA to go? Tim explained that there are two avenues to access this medication, namely: 1) through the physicians office which is done through HCPCS J-code billing, and 2) through POS with a prior authorization through the pharmacy. A physicians office must obtain and bill. Volume from the past year has been low. The discussion centered on the many off-label uses in various settings and the consensus that individual cases for these uses through a pharmacy setting should be considered on an individual case by case basis. It was pointed out that when administered through a physicians office we have no way of knowing what it is being used for. Tim emphasized that the department would like to keep the use within the physicians office setting where it is mostly centered now. That allows the physician to use it for his difficult cases without having to go through a PA process. The question was asked about nursing home patients with cerebal palsay that cannot go to the doctors office for administration and how that may affect patient access if it cannot be obtained through a pharmacy because of mobility issues. Tim stressed that that is not a patient access problem, it is a physician access problem. The system cannot solve every problem or make it as less problematic as possible for everyone beyond the patient. The department is making it available and covering it. Brad proposed that coverage through a pharmacy be with prior authorization with the criteria presented. Jeff seconded the motion. Don rephrased the proposal for clarification of coverage through each route of access. Motion passed unanimous.

5. Over active bladder- Criteria review

This item was requested by Dr. Kevin Stigge, MD, a private physician practicing in Salt lake City, who requested time to address the Board on the topic. Dr. Stigge's disclosure provided to the board states that, " I will be attending the meeting on behalf of my patients with no compensation from a pharmaceutical company. In the past I have spoken for pharmacetuical

companies on different disease states. Please note I am not being paid by a pharmaceutical company to attend the DUR meeting." Dr. Stigge stated that his concern is to secure better access to better medications than oxybutinin for his patients. In terms of side effects profile, ease of use and efficacy he referred to the impact the over active bladder drugs have on not only the lives of his patients but also nursing home patients. He stated that reduced episodes of incontinence translates into lower cost for medicaid when looking at nursing home pad usage, and the increased incidence of incontinence that occurs when patients go into nursing facilities. He spoke of less effect on the CNS and how that correlates into fewer unassisted middle of the night falls both in home as well as in nursing homes. Dr. Stigge then invited two unannounced physicians to address the Board for the remainder of the time promised to him. RaeDell pointed out that the nursing home patients referred to are no longer part of the Medicaid program. The question was also asked as to how many of the drug plans require step therapy, and it was noted that none require step therapy but they do have tiered co-pays for these drugs. The Board gave permission to Dr. Stuart Landau, a private practice urologist from Utah County to address the Board. He spoke favorably for the long acting bladder anti-spasmodics. Dr. Landau then said he wanted Dr. Lindsay Kerr to use his time. Dr. Kerr reiterated remarks she has offered in previous Board meetings reviewing this class of drugs. She noted that she is a consumer advocate for the Association of Incontinence which has an interest in these medications. Dr. Kerr stated that she receives compensation from all of the pharmaceutical companies for the long acting drugs doing speaking engagements. She estimates that about half of her patients are in the Medicare group. The Board requested a criteria review for this class. A breakdown of these patients over the last two months was requested. Discussion ensued; the Board requested that this item be returned to next months meeting with the class review from the U and a breakdown of the patients using these agents over the last two months.

6. New products and Specialty Pharmacies

A Fact sheet was provided that described the scope of this issue. Tim explained that newer drugs that come to market often begin with very expensive price tags and then are provided through exclusive distribution agreements with a single entity. This presents problems with pharmacist/patient relationships, access, and storage and handling. These are seen as mail-order arrangements. The department proposed the following policy:

1) New injectable drugs will be provided via J-code administration in a doctor's office until DUR review can be undertaken.
2) New oral meds will be provided without a PA until DUR Board review can be undertaken.
   a. The department may use other means of control such as quantity limitations
   b. If a new drug pertains to a category already under prior authorization, it will be placed under prior until DUR review
   c. Specialty pharmacy drugs will be otherwise provided with a Utah MAC
3) The manner of reimbursement calculation will be addressed. Efforts will be made to identify specialty pharmacies and reimbursements will be limited to AWP-35%. Medicaid will not reimburse a third party for any drug. Medicaid only reimburses physicians via J-code billing or pharmacies through point-of-sale.

It was moved and seconded to approve this criteria and continue this discussion at next months meeting. Vote was unanimous.

Next meeting set for April 13, 2006
Meeting adjourned.

The DUR Board Prior approval sub-committee convened and considered 8 petitions.